



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2019-N-5666, FDA-2011-N-0231, FDA-2010-N-0161, FDA-2011-N-0275, and FDA-2013-D-0575]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <http://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Table 1.--List of Information Collections Approved By OMB

Title of Collection	OMB Control Number	Date Approval Expires
Empirical Study of Promotional Implications of Proprietary Prescription Drug Names	0910-0896	4/30/2023
Adverse Experience Reporting for Licensed Biological Products; and General Records	0910-0308	4/30/2024
Export Certificates for FDA Regulated Products	0910-0498	4/30/2024
Certification to Accompany Drug, Biological Product, and Device Applications or Submissions	0910-0616	4/30/2024
Expedited Program for Serious Conditions-Drugs and Biologics	0910-0765	4/30/2024

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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